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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/897,441 07/21/97 FIBI

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EXAMINER

HM12/0925

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ART UNIT

PAPER NUMBER

1642

DATE MAILED:

09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/897,441

Applicant(s)

Fibl et al

Examiner

Karen Canella

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– Th MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-7, 9-12, and 14-23 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9, 14-16, and 22 is/are allowed.
- 6) ☒ Claim(s) 5-7, 10-12, 17-21, and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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Response to Arguments

1. Claims 5-7, 9-12 and 14-23 are pending and under consideration.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
3. The rejection of claims 6, 7, 11 and 17-21 is re-made for the reasons of record as stated in Paper No. 12, as the examiner inadvertently withdrew this rejection in Paper No. 16.
4. Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Sytkowski et al (Journal of Biological Chemistry, 1987, Vol. 262, pp. 1161-1165). Claim 17 is drawn to an anti-erythropoietic antibody directed against epitopes that bind to the EPO receptor. Claim 18 embodies an antibody which neutralizes the biological activity of EPO. Claim 19 embodies a monoclonal antibody. Sytkowski et al disclose neutralizing antibodies to EPO, anti-peptide 99-118 and anti-peptide 11-129, that bind to the receptor binding domain of EPO (page 1165, last paragraph).
5. The rejection of claims 5, 6, 11, 12, 17, 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin (US 4,703,008). Claim 5 is drawn in part to a method of using an EPO peptide for the preparation of an antibody, wherein the EPO peptide consists essentially of a peptide of less than the complete EPO protein, the peptide selected from the group consisting of amino acid positions 152 to 166 (P2/1). Claim 6 is drawn to an antibody directed against an EPO peptide, wherein said EPO peptide consists essentially of a peptide less than the complete EPO protein, said peptide having the sequence of amino acid positions 152 to 166 (P2/1). Claims 11 and 12, claim the same antibody for the detection of EPO. Claim 20 further embodies a diagnostic aid for the detection of EPO. Claim 23 embodies an anti-EPO receptor as in claim 6,

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directed against EPO epitopes which bind the EPO receptor. As the claims 5, 6, 11 and 12 are drawn to peptides less than the complete EPO protein consisting essentially of amino acids 152 to 166 of the EPO protein, and Lin et al has disclosed the polyclonal antibodies produced by immunization of the peptide defined by 144-166 of EPO which produces neutralizing polyclonal antibodies which bind to EPO, the antibodies disclosed by Lin et al are the same as those claimed.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sytkowski et al (Journal of Biological Chemistry, 1987, Vol. 262, pp. 1161-1165) in view of Yanagawa et al (Blood, 1984, Vol. 64, pp. 357-364). Claim 10 is drawn to a method of using the antibody of claim 6 for the purification of EPO. Sytkowski et al teaches the antibody of claim 6 for the reasons set forth in paragraph 4, supra. Sytkowski et al does not disclose a method of purification of EPO based on the use of said antibody. Yanagawa et al teach a method of purifying human erythropoietin from urine by using separations methods based on monoclonal antibodies to human erythropoietin. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute the taught by Sytkowski et al in the method of purification of erythropoietin. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Yanagawa et al on the successful purification of human erythropoietin by the use of immunoadsorbent chromatography using monoclonal antibodies which specifically bind to erythropoietin.

7. Amendments of all the claims to read on a peptide "consisting of" the instant disclosed epitopes would obviate the prior art rejections.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner


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can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

September 23, 2001


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